IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

In re Ethicon, Inc. Pelvic Repair System Products Liability Litigation	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: *Cutter v. Ethicon, Inc.* 2:12-cv-01790; *Bates v. Ethicon, Inc.* 2:12-cv-02020; *Daugherty v. Ethicon, Inc.* 2:12-cv-02076; *Morrison v. Ethicon, Inc.* 2:12-cv-02141; and *Miller v. Ethicon, Inc.* 2:12-cv-02187	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE EXPERT TESTIMONY OF MICHAEL KARRAM, MD

Plaintiffs in the above-captioned consolidated case respectfully move this Court to exclude the testimony of Michael Karram, M.D., a proffered expert witness for the Defendants, regarding the safety and efficacy of Ethicon's Prolift and TVT-O mesh products. Dr. Karram does not possess the necessary qualifications to render many of his opinions, which is the first requirement for an expert witness to satisfy under the Rules. He selectively reviewed and considered data – even within the same source – which is an unacceptable methodology. Dr. Karram's personal experience and practicing opinions differ from his litigation opinions. Finally, Dr. Karram did not analyze or explain contrary data when reaching his opinions. Dr. Karram's opinions do not satisfy the requirements for expert witness testimony as set forth in Rule 702 and under the *Daubert* standard and he should not be allowed to testify as an expert witness.

INTRODUCTION

Dr. Michael Karram seeks to testify that the Prolift device is safe and effective for treating pelvic organ prolapse. Purportedly based on his personal experience and the relevant medical

literature, Dr. Karram has concluded that the perceived benefits associated with Prolift outweigh its potential risks. Dr. Karram has not established that he followed a reliable methodology in evaluating either the risks or the benefits associated with Prolift.

Instead, Dr. Karram has employed a flawed, unreliable methodology to reach his opinions. The numerous methodological flaws include:

1) Dr. Karram admits that strong evidence shows that Prolift is associated with an exposure rate which exceeds what he considers to be an acceptable rate;
2) Dr. Karram relies on outdated evidence regarding the safety and efficacy of Prolift when more recent analyses by the same authors reach contrary conclusions;
3) Dr. Karram relies on outdated evidence regarding the efficacy of native tissue repair when the same authors have recently reanalyzed the original data and changed their findings;
4) Dr. Karram admits that Prolift should be reserved for high-risk patients and not used as a primary treatment for prolapse, which undermines his general opinions here; and
5) Dr. Karram selectively relies on findings from evidence that support his opinions but ignores contrary findings and conclusions from that same evidence.

Dr. Karram offers additional opinions regarding the adequacy of Ethicon's warnings in its TVT-O and Prolift IFUs and patient brochures and regarding the biomechanical aspects of the mesh used in the Prolift device. Dr. Karram has not followed a reliable methodology regarding these other opinions. Because Dr. Karram has not established that he followed a reliable methodology to reach his opinions, Plaintiffs respectfully request that the Court exclude Dr. Karram's opinions and testimony.

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient

> facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. On the issue of qualifications, "the district court must decide whether the expert has 'sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case.'" *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)).

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury—i.e., whether it is relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). The relevance aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

To meet the standard of reliability, the testimony "must be supported by appropriate validation—i.e., 'good grounds,' based on what is known. In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383 (4th Cir. 1995). The function of the Court is to act as a gatekeeper when it comes to expert testimony: "[E]xpert witnesses have the potential to be both powerful and quite misleading[;]" and it is incumbent upon the Court to "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) and *Daubert*, 509 U.S. at 588, 595).

Courts should focus on expert witnesses' "principles and methodology, not on the conclusions that they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). This is because "*Daubert* governs whether evidence is admitted, not how persuasive it must be to the factfinder." *Cavallo*, 100 F.3d at 1158. The court has considerable discretion in determining an expert witness' testimony is admissible and whether the expert should be admitted or excluded. "[T]he trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire,* 526 U.S. at 152). In addition to specific legal citations and argument contained in this Memorandum, Plaintiffs incorporate by reference the standard of review for *Daubert* motions set forth by this Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 692, 701 (S.D. W. Va. 2014).

ARGUMENT

As noted above, there are several reasons that this Court should prohibit Dr. Karram, a urogynecologist designated as a Defense expert, from giving opinions about the safety and efficacy of the Prolift product, the appropriateness of the training methods Ethicon used, biomaterial properties, and the adequacy of the IFU.

I. DR. KARRAM USED A FLAWED METHODOLOGY TO REACH HIS OPINIONS REGARDING THE SAFETY AND EFFICACY OF PROLIFT.

Dr. Karram seeks to offer the opinion that the Prolift device was safe and effective. *Report* at 14 (attached as Exhibit 2). Dr. Karram concludes that the perceived benefits of Prolift outweigh the potential risks and stated that his opinions are based upon his experience and review of the medical literature. However, Dr. Karram did not follow a reliable methodology in assessing the risk-benefit profile of Prolift and reaching his opinions.

A. Dr. Karram employs an inconsistent and selective approach when evaluating the risks associated with the Prolift device.

Dr. Karram states that the Prolift device is not associated with an increase in complications as compared to other procedures to treat POP. When discussing the available Prolift studies, Dr. Karram testified that "[o]verwhelmingly, they consistent [sic] show the success of Prolift at achieving long-lasting anatomic cure with a low rate of complications." *Report* at 17. Yet, in his deposition, Dr. Karram acknowledged that more recent evidence shows Prolift is associated with an exposure rate that exceeds what he considers is acceptable.

In his report, Dr. Karram selectively discussed findings from the 2016 Cochrane review looking at native tissue repair compared to transvaginal mesh. *Report* at 18. The 2016 Cochrane review concluded "The risk-benefit profile means that transvaginal mesh has limited utility in primary surgery. While it is possible that in women with higher risk of recurrence the benefits may outweigh the risks, there is currently no evidence to support this position."[1]

In his report, Dr. Karram opined, "An overall mesh exposure rate of 3%-8% is an acceptable rate by today's standards." *Report* at 19. Yet, one of the most recent and powerful studies, that he cites and relies upon, found a 12% exposure rate. Karram dep. 102:13-23 (attached as Exhibit 3). Dr. Karram's opinion regarding the safety of the Prolift device is the product of an unreliable methodology because he admits that evidence shows Prolift device is associated with an exposure rate 50% higher than what he considers acceptable. Karram dep. 104:13-24. He does not address or critique this contrary, powerful evidence. Instead, he admits that this exposure rates findings fails to meet his standard for what is acceptable. Karram dep. 105:12-15 ("Q: So if, in fact, the exposure rate was 12 percent, that would be above the standard by today's standards? A: I would think so, yes.").

[1] Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Marjoribanks J. Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse. Cochrane Database of Systematic Reviews 2016, Issue 2. Art. No.: CD012079. DOI: 10.1002/14651858.CD012079.

Dr. Karram also acknowledged that another piece of evidence he relied upon, the ACOG Committee Opinion, found that a "small but significant group of patients [] experience permanent and life-altering sequelae, including pain and dyspareunia, from the use of vaginal mesh."[2] Karram dep. 80:23-81:14. Dr. Karram testified that he simply disagrees with their statement. Karram dep. 81:15-17. However, Dr. Karram also testified that the he considered ACOG and other organizations' analyses of the evidence important enough to include in his report and that he relied upon them. Karram dep. 84:16-22.

Dr. Karram's method for concluding that Prolift is safe is fundamentally flawed and based on outdated and inaccurate data. Dr. Karram admits as much and further admits that the more recent data is accurate and reliable. His failure to address this inconsistent data renders his opinions unsound.

B. Dr. Karram employed an unreliable methodology in assessing the benefits associated with the Prolift device.

One of the reasons Dr. Karram states the Prolift device had a positive risk-benefit profile is because, in his opinion, alternative procedures such as native tissue repair were less effective than the Prolift device. *Report* at 10 ("Failure rates have been shown to be extremely high for native tissue repairs."). When reaching this opinion, Dr. Karram ignored more recent publications as well as contrary statements even within the studies he cited.

Dr. Karram opines that Prolift was more efficacious than native tissue repairs. He testified that low success rates with native tissue repair were "frequently cited as a reason why innovations such as vaginal mesh were needed to decrease failure rates." Karram dep. 87:2-7. In support of this opinion, Dr. Karram cited the 2001 Weber study.

[2] Vaginal placement of synthetic mesh for pelvic organ prolapse. Committee Opinion No. 513. American College of Obstetricians and Gynecologists. Obstet Gynecol 2011;118:1459–64, reaffirmed in 2015.

However, a recent ACOG Committee Opinion noted that the authors of the Weber study recently reanalyzed the original data using "modern outcome measures" and found that the "revised success rates for the three arms of this RCT were comparable, with 89 percent of women having no objective prolapse…" Karram dep. 87:8-16. Dr. Karram was aware of the reanalysis of this data as evidenced by its inclusion on his reliance list, yet he chose to cite and discuss the only the old data which supported his opinion – that Prolift was safe because the alternative native tissue repair was ineffective. Dr. Karram admitted that the reanalysis of the native tissue repair data showed that the success rate was "pretty good". Karram dep. 87:17-20 ("Q: And you would agree that an 89 percent success rate is pretty good? A: In the hands of one surgeon, yes."). However, he did not discuss, nor rely upon, the more updated, peer-reviewed data in his report or in reaching his opinions. This is improper methodology.

Dr. Karam also cites to the 2013 Cochrane review by Maher as support for his opinion that the Prolift device was safe and effective because native tissue repair was ineffective. "According to the latest Cochrane review (Maher 2013) of 5,954 women, traditional repair was associated with a higher anterior compartment recurrence on exam than any of the mesh repairs (CI 2.50-3.96)." *Report* at 15.

However, he later testified that his Report was not actually discussing the latest Cochrane review. Karram dep. 94:11-18. He admitted that the data he included in his Report regarding the efficacy of native tissue repairs was outdated by the more recent Cochrane review and that he needed to update his Report. Karram dep. 94:19-95:3. Importantly, the updated 2016 Cochrane review changed its conclusions regarding the safety and efficacy of Prolift as compared to native tissue repair. In fact, the 2016 Cochrane review found that mesh repairs like Prolift were "associated with higher rates of reoperation for prolapse, stress urinary incontinence, or mesh

exposure and higher rates of bladder injury at surgery and de novo stress urinary incontinence." Karram dep. 96:24-97:7.

Dr. Karram also acknowledged that the ACOG review found that the "rate of reoperation to correct complications, as well as the total reoperation rate, was highest for vaginal mesh kits compared with vaginal native tissue and abdominal repairs…" Karram dep. 75:14-21. Dr. Karram agreed with this statement. Karram dep. 76:10-21

Further, Dr. Karram's personal experience performing native tissue repairs, upon which he relies in reaching his opinions, also contradicts his litigation opinion that native tissue repairs are ineffective.

Q: Do you have good results with native tissue repair?
A: It depends on the procedure. It depends on the procedure and the anatomy we're dealing with.
Q: So is that a yes?
A: Yes.

Karram dep. 26:1-6. Based on Dr. Karram's personal results performing native tissue repair, he acknowledged that he performed this technique on the majority of the patients he treated. To then claim that native tissue repair was less effective than mesh repair is unreasonable and contradictory and reflective of a flawed methodology.

In sum, Dr. Karram admitted his opinion that Prolift was more efficacious and safer than native tissue repair was based on unreliable, outdated data. He admitted that more recent, better studies directly contradicted his opinions. Yet, he failed to discuss or even address this contradictory data in his report. Accordingly, Dr. Karram's opinions are not based on reliable scientific data or methods.

C. Dr. Karram's litigation opinions are contrary to his own medical opinions and surgical practice.

Based on the increased complications associated with Prolift, and the similar success rates with other procedures like native tissue repair, the Prolift device is not safe and effective as a primary treatment for prolapse. At best, Prolift should be reserved for high risk patients. In his deposition, Dr. Karram admitted as much – which is contradictory to his written opinions issued in this matter.

In his report, Dr. Karram states that the Prolift device is appropriate for primary treatment of pelvic organ prolapse. However, in his deposition when confronted with the 2016 Cochrane Review, he changed his mind. The 2016 Cochrane review concluded, "The risk-benefit profile means that transvaginal mesh has limited utility in primary surgery."[3] Karram dep. 97:16-20. And, importantly, in his deposition Dr. Karram agreed. Karram dep. 89:3-6 ("Q: So you would agree with the author's statement here, that mesh kits such as Prolift should be reserved for high-risk patients? A: I do.").

The 2016 Cochrane review further noted, "While it is possible that in women with higher risk of recurrence the benefits may outweigh the risks, there's currently no evidence to support this proposition." 2016 Cochrane Review Summary at 3; Karam dep. 98:3-8. However, Dr. Karram was necessarily forced to disagree with this conclusion and he acknowledged that he did not discuss, analyze, or criticize this conclusion by the Cochrane review that is contrary to his opinions here. Karram dep. 98:9-16. Instead, Dr. Karram testified that the Cochrane review is powerful evidence. He testified that the Cochrane group is very reputable, that their systematic review is Level 1 evidence, representing the highest available evidence, and that he relies upon them here. Karram dep. 100:16-101:6. Additionally, Dr. Karram agreed that the Cochrane review

[3] Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Marjoribanks J. Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse. Cochrane Database of Systematic Reviews 2016, Issue 2. Art. No.: CD012079. DOI: 10.1002/14651858.CD012079, at 3.

correctly looked at and evaluated the relevant evidence. Karram dep. 99:23-100:3; Karram dep. 101:7-10. Dr. Karram agreed with their analysis, methods, and findings, but he simply disagreed with their conclusions without being able to offer any criticism or explanation. Karram dep. 101:11-18.

For the reasons set forth above, Dr. Karram's methodology relating to the evaluation of the safety and efficacy of the Prolift device was improper and his opinions should be excluded in their entirety.

II. DR. KARRAM EMPLOYED AN UNRELIABLE METHODOLOGY WHEN REACHING HIS OPINIONS REGARDING THE ADEQUACY OF ETHICON'S WARNINGS FOR THE PROLIFT AND TVT-O DEVICES

Dr. Karram opines that Ethicon provided adequate warnings in its TVT-O and Prolift IFUs and patient brochures. Dr. Karram did not employ a reliable method to reach these opinions, in part, because he has not reviewed any of the regulatory or internal Ethicon requirements for warnings. Karram dep. 58:12-59; 107:8-10. Based on Dr. Karram's misunderstanding of warning requirements, he does not think a manufacturer has to warn about any of the risks at issue here. *See Report* at 11 ("There is no need for a manufacturer or any other non-educational entity to inform surgeons of these risks."). Dr. Karram does not possess the qualifications to testify about the adequacy of the warnings in the IFU and he did not perform an adequate review of the necessary materials relevant to these opinions. His opinions related to the adequacy of the warnings related to the Prolift and TVT-O devices should be excluded in their entirety.

A. Dr. Karram does not possess the necessary qualifications to opine on the adequacy of the warnings contained in Ethicon's IFUs.

On the issue of qualifications, "the district court must decide whether the expert has 'sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case.'" *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012)

(quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)). Only after this criterion related to qualifications is satisfied does the *Daubert* standard apply. Dr. Karram does not possess the necessary qualifications to opine about the adequacy of the warnings contained in Ethicon's IFUs.

Dr. Karram readily admits he is "not a regulatory expert…" *Report* at 22. More importantly, Dr. Karram has not reviewed the relevant regulations regarding warning requirements. Dr. Karram states that one of the bases for his opinions regarding the adequacy of Ethicon's warnings is his review of 21 C.F.R. 801.109(c). *Report* at 22; Karram dep. 58:7-11. Dr. Karram argues that 21 C.F.R. 109 excuses Ethicon from warning about risks associated with Prolift. When asked how he decided that Section 109 is applicable here, Dr. Karram testified that he did not actually read the entire regulation. Karram dep. 58:12-59:13 ("I did not read the whole thing."). Dr. Karram does not possess the required qualifications and did not undertake the necessary steps to inform his opinions and, as such, he should not be allowed to present these opinions to a jury.

B. Dr. Karram should not be allowed to testify about what "all surgeons" know or about the "general knowledge" of all surgeons

Dr. Karram's opinion that Ethicon adequately warned is simply based on his own personal opinion that all doctors already know the risks. He repeatedly makes statements such as "It is common knowledge to pelvic floor surgeons that any surgery for stress urinary incontinence or pelvic organ prolapse … can potentially cause complications …" *Report* at 20, and "[T]he actual surgical risks and complications … are commonly known to pelvic floor surgeons." *Report* at 21-22. As discussed below, Dr. Karram admits not all doctors have his level of knowledge regarding Prolift. However, even if all doctors had his level of knowledge, he cannot provide any reliable

basis for his proposition that this would excuse Ethicon from warning about the risks associated with Prolift.

Dr. Karram has worked as a consultant for Ethicon which has afforded him opportunity to learn extensive information about these products. Obviously, not all doctors are similarly situated. He admitted that not all doctors have time to review all the literature and that some doctors are not as knowledgeable about the Prolift literature as others. Karram dep. 30:1-10; 112:17-21. Further, Dr. Karram testified he was more knowledgeable as compared to other doctors about the Prolift medical literature. Karram dep. 30:11-21; 112:17-113:4.

Dr. Karram acknowledged that he has no evidence or scientific basis for assertions regarding the "general knowledge" of surgeons. Karram dep. 112:8-11. Dr. Karram testified that he has not undertaken any attempt to survey or poll other doctors as to what they commonly know. Karram dep. 112:14-16. Instead, Dr. Karram has acknowledged that many of the organizations he relied upon, such as ACOG and AUGS, have stated that some doctors needed more information regarding complications associated with the Prolift device. Karram dep. 72:23-73:20.

C. Dr. Karram did not perform an adequate review of the available information in reaching his opinions which renders them unreliable.

Dr. Karram also opines that Ethicon provided adequate warnings in its TVT-O and Prolift patient brochures. However, Dr. Karram admits that he never discussed any of the brochures or any of their warnings in his Report. Karram dep. 106:5-10 ("I didn't discuss them, no.")

Similarly, Dr. Karram never reviewed any of the regulatory requirements for patient labeling. Karram dep. 106:23-107:4 ("No. I didn't even know there was regulation for patient labeling."). Additionally, Dr. Karram did not review any of Ethicon's internal standards regarding patient labeling. Karram dep. 107:5-7. His opinions regarding the adequacy of patient labeling have no reliable basis and is therefore not the product a reliable methodology.

Dr. Karram's opinions that Ethicon provided adequate warnings are not based on any reliable methodology because he has not reviewed the relevant standards and does not possess the necessary qualifications. Dr. Karram's opinion that all of the risk information regarding Prolift and TVT-O is common knowledge to all surgeons is also unreliable. As such, Dr. Karram's opinions regarding the adequacy of Ethicon's warnings in the IFU and patient brochures should be excluded.

III. DR. KARRAM'S OPINIONS REGARDING THE BIOMECHANICAL ASPECTS OF THE PROLIFT MESH ARE BASED ON AN UNRELIABLE METHODOLOGY BECAUSE HE HEAVILY RELIES UPON STUDIES REGARDING MID-URETHRAL SLINGS AND DOES NOT EXPLAIN CONTRARY EVIDENCE.

Dr. Karram opines that the specific mesh used in the Prolift product is safe for permanent implant to treat POP. Yet, Dr. Karram does not cite to any scientific literature specifically evaluating the biomechanical safety of the Prolift mesh. Instead, he inappropriately relies upon evidence regarding mid-urethral slings ("MUS") used to treat stress urinary incontinence ("SUI"). Additionally, Dr. Karram refuses to address evidence that contradicts his opinions regarding the biomechanical properties of the Prolift mesh, even though he was aware of the evidence. Dr. Karram's opinions regarding the biomechanical properties of the mesh are not the product of a reliable methodology.

A. Dr. Karram improperly relies upon mesh sling literature to support his opinions on the Prolift device.

Dr. Karram states that the Prolift mesh is safe and effective and cites to studies regarding mid-urethral sling ("MUS") devices used to treat incontinence. For example, Dr. Karram cites to the Nilsson 2013 study (regarding MUS), a 2014 AUGS SUFU Position Statement on Mesh MUS for SUI, and a 2015 Cochrane review regarding MUS. *Report* at 12. Dr. Karram states that the MUS data "bears on the mesh material in Prolift because they are both made of the same polypropylene materials." *Report* at 24. Dr. Karram cannot cite to any evidence for his proposition

that the MUS evidence somehow establishes the safety and efficacy of the Prolift mesh. Karram dep. 51:20-24.

B. Dr. Karram does not possess the necessary qualifications to opine on the biomechanical properties of mesh

Dr. Karram admits he is not a biomechanical engineer and would defer to a biomechanical expert regarding the differences between the Prolene mesh used in the MUS and the Prolene Soft Gynemesh that is used in the Prolift. Karram dep. 53:9-17. Dr. Karram admits there are many differences between the MUS device and the Prolift device. The MUS device uses a much smaller piece of mesh compared to the Prolift implant. Karram dep. 54:3-6. These MUS devices are a completely different mesh construction than that used in the Prolift device, with a different pore size and different weight. Karram dep. 49:14-50:12. Dr. Karram admits he does not know the clinical impacts of these biomechanical differences. Karram dep. 53:18-54:2.

Foreign Body Reaction

Dr. Karram opines that the Prolift mesh elicits a foreign body reaction once implanted that stops around six to eight weeks. Karram 107:11-20. When asked what evidence he relies upon for this opinion, Dr. Karram testified that he could not identify any specific study. Karram dep. 107:21-108:7. He vaguely remembered some study of explanted mesh done in rats, "It's a study that – I think it was quoted with – what's his name – I can't remember. I do have a study. I don't know which one it is…." Karram dep. 107:21-108:7.

Degradation

Dr. Karram states, "There is no clinical significance to claims of alleged particle loss and mesh degradation over time." *Report* at 27. Dr. Karram explains that this opinion is based on his "recent medline search on degradation and particle loss [that] revealed no scientific data to support

this theory." *Report* at 28. While Dr. Karram stated that he could not find any of the evidence showing degradation or particle loss, somehow this evidence was included on his reliance list.

Similar to many other opinions offered by Dr. Karram, he does not possess the qualifications nor did he undertake the appropriate review to present these opinions to a jury. The opinions of Dr. Karram related to the biomechanical properties of mesh should be excluded in their entirety.

CONCLUSION

The methodology employed by Dr. Karram in reaching his opinions does not satisfy the requirements for expert witness testimony as set forth in Rule 702 and under the *Daubert* standard. Dr. Karram does not possess the necessary qualifications to render many of his opinions, which is the first requirement for an expert witness to satisfy under the Rules. He selectively reviewed and considered data – even within the same source – which is an unacceptable methodology. Dr. Karram's personal experience and practicing opinions differ from his litigation opinions. Finally, Dr. Karram did not analyze or explain contrary data when reaching his opinions. For the reasons stated above, Plaintiffs respectfully request this Court exclude Dr. Karram's opinions in their entirety.

Respectfully submitted this 21st day of July, 2016.

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CERTIFICATE OF SERVICE

I hereby certify that on July 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the list of participants registered to receive service in this MDL.

/s/ Joseph J. Zonies